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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,376

05/19/2005

Joseph Powers

26227-A USA

9338

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Sanofi-Aventis

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PHILADELPHIA, PA 19103-3291

EXAMINER

PAULS, JOHN A

ART UNIT

PAPER NUMBER

4114

MAIL DATE

DELIVERY MODE

02/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,376	<b>Applicant(s)</b> POWERS ET AL.	
	<b>Examiner</b> JOHN A. PAULS	<b>Art Unit</b> 4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**Status of Claims**

1. This action is in reply to the application filed on 19 May, 2005
2. Claims 1 - 16 are currently pending and have been examined.

***Specification***

3. The disclosure is objected to because of the following informalities: use of acronyms. Specifically, on page 9 the terms "BMI calculator" and "PCA device" are used. For purposes of this examination, Examiner assumes these terms mean "Body Mass Index calculator" and PDA device" respectively.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:  
  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
5. Claims 1 – 4, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The steps recited do not qualify as a statutory process. In order for a method to be considered a "process" under §101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and is non-statutory subject matter. Although the steps are performed using a computer, the computer is a field of use limitation because the steps are human actions that do not require (i.e. are not tied to) the computer.

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6. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1 – 3, 6 - 9 and 12 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al. (US 5769074 A) and in further view of Herren et al. (US 6108635 A) and in further view of Teagarden et al. (US 6014631 A).

**CLAIMS 1 – 3, 6 - 9 and 12 - 14**

Barnhill as shown discloses the following limitations:

- *comparing, using a processing device, patient profile information for one or more patients with said treatment regimen;* (see at least Barnhill column 8 line 6 – 10 and column 7 line 41 – 64);

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- *recommending a specific treatment regimen for one or more of said patients whose patient profile information was subjected to said comparison step, based on said comparison results; (see at least Barnhill column 23 line 51 – 59 and column 8 line 6 – 10);*
- *outputting said comparison results; (see at least Barnhill column 8 line 6 – 14);*
- *gathering said patient profile information; (see at least Barnhill column 12 line 4 – 18);*
- *obtaining basic profile information for each of said one or more patients; (see at least Barnhill column 12 line 4 – 8);*
- *obtaining visit-specific profile information for each of said one or more patients; (see at least Barnhill column 12 line 9 – 18).*

Barnhill as shown discloses the limitations shown above. Barnhill does not disclose the following limitations, however Herren does:

- *study data pertaining to said treatment regimen; (see at least Herren column 12 lines 4 – 10);*
- *gathering said study data pertaining to said treatment regimen; (see at least Herren column 12 lines 4 – 10);*
- *storing said study data in a memory accessible by said processing device; (see at least Herren column 12 lines 4 – 10);*
- *an output device, coupled to said processor, for displaying said recommended treatment regimen; (see at least Herren column 11 lines 7 – 13 and line 42 - 53);*
- *an input device, coupled to said processor, for inputting said patient profile information; (see at least Herren column 11 lines 42 – 53);*
- *a storage device, coupled to said processor, for storing said patient profile information; (see at least Herren column 11 lines 42 – 53);*
- *means for inputting study data pertaining to said treatment regimen; (see at least Herren column 14 lines 12 – 39);*
- *a storage device for storing said study data; (see at least Herren column 11 lines 42 – 53);*
- *computer-readable means; (see at least Herren column 11 lines 42 – 53);*

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It would be obvious to one of ordinary skill in the art at the time of the invention to modify the computer assisted diagnosis and treatment method of Barnhill with the disease information system of Herren because using study data to diagnose and recommend treatments allows practitioners to take advantage of the prior knowledge gained by researchers through clinical trials.

The combination of Barnhill/Herren discloses the limitations shown above. Barnhill/Herren does not disclose the following limitations, however, Teagarden does:

- *storing said patient profile information in a memory accessible by said processing device; (see at least Teagarden column 13 lines 4 – 15).*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the computer assisted diagnosis and treatment method of Barnhill/Herren with the medication review system of Teagarden because storing patient information allows for an on-going review of the effects the treatment are having on a patient.

**10.** Claims 4, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al. (US 5769074 A) and in further view of Herren et al. (US 6108635 A) and in further view of Teagarden et al. (US 6014631 A) and in further view of Applicants Own Admission.

#### **CLAIMS 4, 10 and 15**

The combination of Barnhill/Herren/Teagarden as shown discloses the limitations above.

Barnhill/Herren/Teagarden does not disclose the following limitations, however, Levy does:

- *study data comprises data from the Heart Outcomes Prevention Evaluation (HOPE) study; (see at least Levy column 19 line 39 – 47).*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the computer assisted diagnosis and treatment method of Barnhill/Herren/Teagarden with the use of the HOPE study as disclosed in Levy because the use of qualified studies to recommend treatment options provides the most up to date and effective treatment options available.

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Additionally, Applicant's Own Admission in the disclosure of the present application (see page 2) that the Hope study data has been used to evaluate the treatment of a particular condition constitutes prior art.

11. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al. (US 5769074 A) and in further view of Herren et al. (US 6108635 A) and in further view of Teagarden et al. (US 6014631 A) and in further view of Edelson (US 6251608 B1).

#### **CLAIMS 5 and 11**

The combination of Barnhill/Herren/Teagarden as shown discloses the limitations above.

Barnhill/Herren/Teagarden does not disclose the following limitations, however Edelson does:

- *processing device comprises a PDA; (see at least Edelson column 7 line 64 to column 8 line 3).*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the computer assisted diagnosis and treatment method of Barnhill/Herren/Teagarden with the prescription creation system of Edelson because PDA's allow practitioners to receive and manipulate data of all kinds during a patient care event thus giving faster results.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haq et al. (US PG PUB 2002/0095313 A1) and in further view of Herren et al. (US 6108635 A).

#### **CLAIM 16**

Haq as shown discloses the following limitations:

- *a recording device configured to solicit patient profile information for one or more patients; (see at least Haq paragraph 0080);*
- *a storage device, couple able to said recording device, storing said patient profile information; (see at least Haq paragraph 0055*
- *a processor configured to; (see at least Haq paragraph 0055);*
  - *compare said patient profile information with data stored in database; (see at least Haq paragraph 0097)*

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- *issue a recommendation recommending said treatment regimen for each patient having patient profile information that indicates, based on said comparison with data, a benefit to be gained from said treatment regimen;* (see at least Haq paragraph 0098)

Haq as shown discloses the limitations shown above. Haq does not disclose the following limitations, however, Herren does:

- *study data stored in said study database;* (see at least Herren column 12 lines 4 – 10).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the computer assisted diagnosis and treatment method of Haq with the disease information system of Herren because using study data to diagnose and recommend treatments allows practitioners to take advantage of the prior knowledge gained by researchers through clinical trials.



### **CONCLUSION**

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **571-270-5557**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

**Commissioner of Patents and Trademarks**

**Washington, D.C. 20231**

or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office**

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Date: 2 February, 2009

/JOHN A. PAULS/

Examiner, Art Unit 4114

/James A. Reagan/

Supervisory Patent Examiner, Art Unit 4114